SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: GABAPENTIN, USP/EP
PRODUCT CODE: 2461
SUPPLIER:
- MEDISCA Inc.
  Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
  661 Route 3, Unit C, Plattsburgh, NY, 12901
  3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
  6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
- MEDISCA Pharmaceutique Inc.
  Tel.: 1.800.665.6334 | Fax.: 514.338.1693
  4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
- MEDISCA Australia PTY LTD
  Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
  Unit 7, Heritage Business Park, 5-9 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE:
- CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
- NSW Poisons Information Centre: 131 126

USES:
Anticonvulsant; analgesic.

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION: Acute Aquatic Toxicity (Category 3)
PICTOGRAM: Not applicable
SIGNAL WORD: Harmful to aquatic life.
HAZARD STATEMENT(S): Not applicable
AUSTRALIA-ONLY HAZARDS: Prevention
Precautionary Statement: Avoid release to the environment.
Response: Not applicable
Storage: Not applicable
Disposal: Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION:
- Health Hazard: 1
- Flammability: 0
- Reactivity: 0
- Personal Protection: E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME: Cyclohexaneacetic acid, 1-(aminomethyl)-
BOTANICAL NAME: Not applicable
SYNONYM: Neurontin
CHEMICAL FORMULA: C₉H₁₇NO₂
CAS NUMBER: 60142-96-3
ALTERNATE CAS NUMBER: Not applicable
MOLECULAR WEIGHT

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>GABAPENTIN</td>
<td>60142-96-3</td>
<td>100</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES

Chemical family: Cyclohexane-acetic acid derivative.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT
Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT
Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED
Call a physician. Wash mouth with water. Do not induce vomiting without medical advice.

IF INHALED
Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

FLAMMABLE PROPERTIES
May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS
Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.
SAFETY DATA SHEET

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in well-closed containers. Store at room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: GABAPENTIN  CAS #: 60142-96-3

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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<td>-</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
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<td>N/L</td>
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</tr>
<tr>
<td>HSE</td>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

EXPOSURE GUIDELINES
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

PERSONAL PROTECTIVE EQUIPMENT

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES
USP: ELV: Industrial: TWA: 1200 µg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Solid</th>
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</thead>
<tbody>
<tr>
<td>DESCRIPTION</td>
<td>White or almost white, crystalline powder.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Sparingly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Not available</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>6.5 - 8 (2%)</td>
</tr>
<tr>
<td>MELTING POINT</td>
<td>(162 - 167)°C, (323.6 - 332.6)°F</td>
</tr>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>FREEZING POINT</td>
<td>(162 - 167)°C, (323.6 - 332.6)°F</td>
</tr>
<tr>
<td>FLASH POINT</td>
<td>Not available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY
Not established.

STABILITY
Stable under recommended storage conditions.

MATERIALS TO AVOID
Strong oxidants.

HAZARDOUS DECOMPOSITION PRODUCTS
Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

HAZARDOUS POLYMERIZATION
Will not occur.

POSSIBILITY OF HAZARDOUS REACTION
Not established.

CONDITIONS TO AVOID
Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY
Oral: Rat: LD50: (mg/kg): > 5000
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION
Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE IRRITATION
Based on available data, the classification criteria are not met.
Irritancy test: Rabbit: Eye: Non-irritating

RESPIRATORY OR SKIN SENSITIZATION
Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Based on available data, the classification criteria are not met. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability).

GERM CELL MUTAGENICITY
Due to lack of data the classification is not possible.
Data from germ cell mutagenicity tests were not found.

CARCINOGENICITY
OSHA: GABAPENTIN is not listed.
NTP: GABAPENTIN is not listed.
IARC: GABAPENTIN is not evaluated.

California Proposition 65
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

NOTES
The physical data presented above are typical values and should not be construed as a specification.
SAFETY DATA SHEET

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met. Suspected carcinogen: CAESAR Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (EXPERIMENTAL value); ISS Carcinogenicity model in VEGA (Q)SAR platform predicts that the chemical is Carcinogen (EXPERIMENTAL value); carcinogen according to ISSCAN.

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met. Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability).

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Symptoms related to the physical, chemical, and toxicological characteristics:


Delayed and immediate effects of exposure:
High blood pressure.

Medical conditions aggravated by exposure:
Active alcoholism. Diabetes. Impaired kidney function.

SIGNS AND SYMPTOMS OF EXPOSURE

May be harmful if inhaled. May cause respiratory tract irritation.

POTENTIAL HEALTH EFFECTS

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion: May be harmful if swallowed.
Skin: May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.
Eyes: May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): 29.88*
EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

Log Pow: -1.31 (20°C).

MOBILITY IN SOIL

Water Solubility: 4490 mg/L (25°C)
Henry’s Law Constant: 1.81E-10 atm-m³/mole (25°C)

OTHER ADVERSE EFFECTS

Not available

NOTES

*Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform prediction (good reliability).

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION
SAFETY DATA SHEET

UNITED STATES & CANADA
UN PROPER SHIPPING NAME Not dangerous good
UN NUMBER Not applicable
CLASS Not applicable
PACKING GROUP Not applicable

AUSTRALIA
UN PROPER SHIPPING NAME Not dangerous good
UN NUMBER Not applicable
CLASS Not applicable
PACKING GROUP Not applicable
HAZCHEM Not applicable

ENVIRONMENTAL HAZARDS Not available
SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.85</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania N/L</th>
<th>N/L</th>
<th>N/L</th>
<th>Right-to-know New Jersey N/L</th>
<th>N/L</th>
<th>Massachusetts N/L</th>
<th>N/L</th>
<th>California Prop 65 N/L</th>
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</thead>
<tbody>
<tr>
<td>GABAPENTIN 60142-96-3</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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<tbody>
<tr>
<td>GABAPENTIN 60142-96-3</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
<td>N/L</td>
</tr>
</tbody>
</table>

SECTION 16: OTHER INFORMATION

REFERENCES

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA - Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

Last Revision: 12/2018
This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.